Exhibit B

Cover Letter

BARD
PERIPHERAL
VASCULAR

2 March 2005

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Re: **"Special" 510(k) Notification**
Recovery® Filter System
Predicate device: Recovery Filter System, K022236, clearance date 11/27/02
and K031328, clearance date 07/25/03

Dear Madam/Sir:

Pursuant to 21 CFR 807.90, Bard Peripheral Vascular, Inc, of C.R. Bard, Inc is submitting two copies of a Special 510(k) notification for the Recovery Filter System and two copies of this cover letter.

The modifications made to the Recovery Filter System are primarily dimensional and is a result of continued product improvement. No material changes or additional components have been incorporated. The spline of the delivery system has been modified to accommodate the geometry modifications made to the Recovery Filter. Design verification was conducted with consideration to FDA's "Guidance for Cardiovascular Intravascular Filter 510(k) Submissions", issued on November 26, 1999.

The terms "substantially equivalent", "similar" and related terms and descriptions in this notification are defined terms or words of art defined by the Food and Drug Administration as those words are used in the Federal Food, Drug and Cosmetic Act as amended and the regulations promulgated thereunder and are not to be construed or interpreted for any other purpose.

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Section 1 of this document contains a signed Truthful and Accurate Statement, a signed Indications for Use Statement, a completed CDRH Premarket Submission Cover Sheet, and the Screening Checklists for "Special" Premarket Notification [510(k)] Submissions with references to the sections of this document that contain the required information. The 510(k) Summary of Safety and Effectiveness Information can be found in Appendix 5.

C.R. Bard, Inc. has not publicly disclosed or acknowledged the fact of its intent to market this product to any individual outside its employ, other than disclosures made under commercial agreements containing appropriate safeguards for secrecy. As a result, C.R. Bard, Inc. requests that the FDA keep and maintain confidential both the existence and the contents of this Premarket Notification in accordance with 21 CFR 807.95(b). C.R. Bard, Inc. also requests that the FDA keep and maintain confidential the contents of this letter.

If you require communications with the manufacturer concerning this notification, the Contact Person is:

Karen Hutchison 480-303-2539

Karen.hutchison@crbard.com 480-449-2546 (fax)

I hereby authorize the FDA to communicate with me regarding this submission via phone, fax and/or email as indicated above. Thank you in advance for your expeditious consideration of this notification.

Sincerely,

Karen Hutchison
Senior Specialist, Regulatory Affairs

BARD
PERIPHERAL
VASCULAR

Recovery® Filter System

Special 510(k)

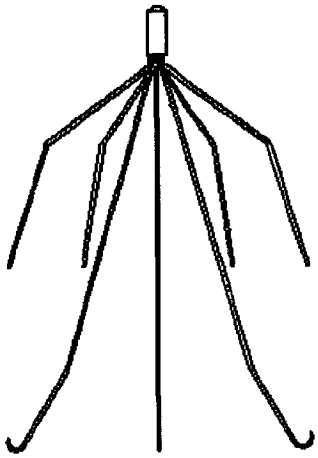
02 March 2005

Bard Peripheral Vascular, Inc
C.R. Bard
1625 West Third Street
P.O. Box 1740
Tempe, AZ 85280-1740

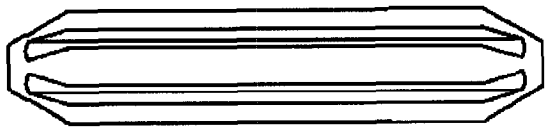
predetermined shape. The delivery system allows the Recovery Filter to be deployed with the filter tip centered and is intended to prevent the legs from crossing while allowing for filter removal when clinically indicated.

An illustration of the Recovery Filter and spline are provided in Figure 1 with key components identified. Engineering drawings are provided in Appendix 4.

Figure 1. Predicate Device



PREDICATE FILTER



PREDICATE SPLINE

B. Subject Device Description

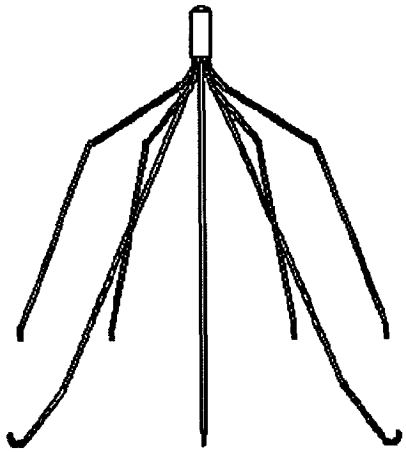
The subject device description is identical to the Recovery Filter System description and indications. The modifications made to the Recovery Filter and delivery system are primarily dimensional. No material changes or additional components have been incorporated.

The predicate filter device has been modified as a result of continued product improvement with the possibility of increasing filter migration resistance and reduction of filter arm fractures. The spline of the predicate delivery system has been modified to accommodate the geometry modifications of the predicate filter. The modifications described in this submission are a result of Bard's effort to manage the lifecycle of the Recovery Filter System product by further improving the product performance.

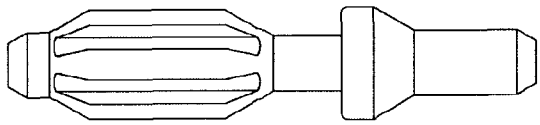
The purpose of this Special 510(k) is to introduce a modified Recovery Filter System with femoral delivery (Item RF-210F).

Illustrations of the subject device filter and spline are provided in Figure 2 with key components identified. Engineering drawings are provided in Appendix 4.

Figure 2. Subject Device



SUBJECT DEVICE FILTER



SUBJECT DEVICE SPLINE

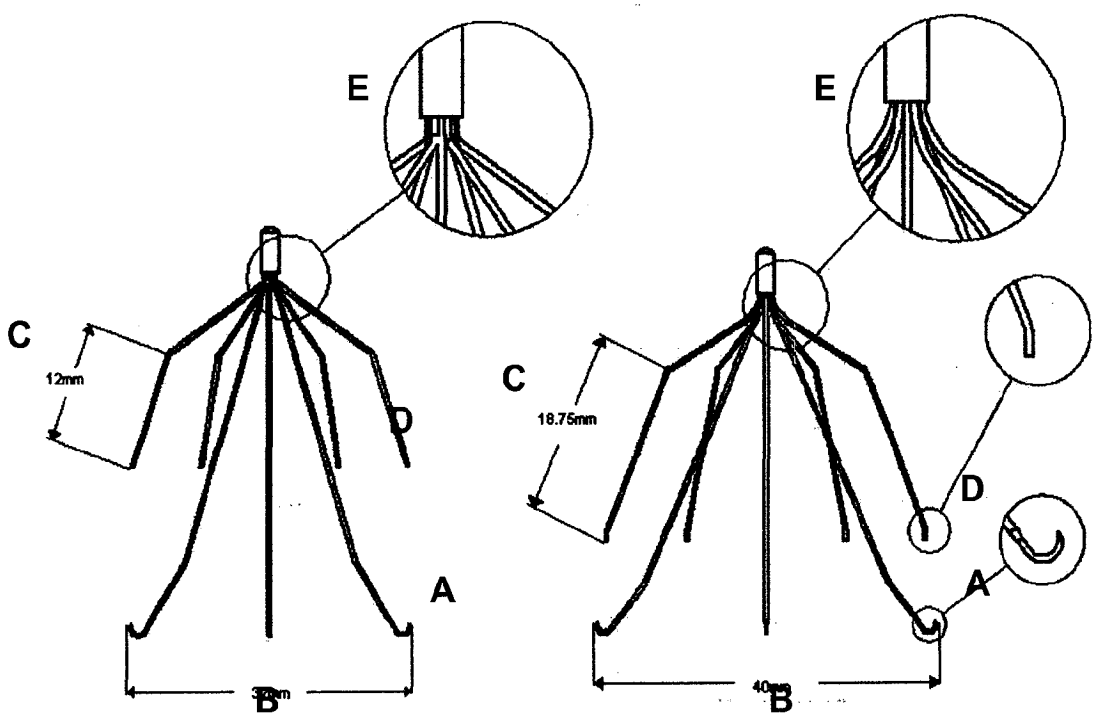
C. Comparison Summary

The differences between the predicate and the subject device are the following:

- Filter hook wire diameter (A)
- Filter leg span (B)
- Filter arm length (C) and geometry (D)
- The curvature of the filter arms at the sleeve (E)
- Delivery system spline (See Figure 1 and Figure 2)

Figure 3. illustrates these differences between the predicate and the subject device.

Figure 3. Illustration of the Differences Between the Predicate and the Subject Devices



PREDICATE DEVICE SUBJECT DEVICE